A study to determine the cardiovascular effects of different methods of administering the oxytocic drug Syntocinon

Submission date	Recruitment status No longer recruiting	Prospectively registered		
12/09/2003		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
12/09/2003		[X] Results		
Last Edited	Condition category	[] Individual participant data		
12/05/2009	Pregnancy and Childbirth			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N0047119214

Study information

Scientific Title

Study objectives

Can we decrease the unwanted effects of syntocinon, namely hypotension and tachycardia, by slowing down the rate of injection?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Prospective randomised controlled single-centre trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Pregnancy and Childbirth: Anaesthesia

Interventions

Bolus injection (bolus group) vs infusion over 5 min (infusion group)

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

syntocinon

Primary outcome measure

Reason for study ie to determine a method that can be used to routinely limit the decrease in blood pressure.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/11/2002

Completion date

31/01/2006

Eligibility

Key inclusion criteria

Women choosing spinal anaesthesia for elective Caesarean:

15 in control group receiving syntocinon 5 units intravenously (IV) as a bolus after delivery 15 in study group receiving syntocinon 5 units IV continuously over 5 min after delivery

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

30

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/11/2002

Date of final enrolment

31/01/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Department of Anaesthesia Birmingham United Kingdom B15 2TG

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type

Government

Website

http://www.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name

Birmingham Women's Healthcare NHS Trust (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2007		Yes	No